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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,322	03/19/2004	Kevin A. Wanasek	P-11455.00	7316
27581	7590	10/21/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			MALAMUD, DEBORAH LESLIE	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/804,322	WANASEK, KEVIN A.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☒ Claim(s) 15 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/26/04</u> , <u>7/06/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

Page 8, paragraph 3, where "FIG. 1" should be changed to "FIG. 1A"

Page 10, paragraph 2, where "FIG. 1" should be changed to "FIG. 1A"

Page 18, paragraph 2, where "FIG. 7A" should be changed to "FIG. 6A"

Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 4, 7-9, 11, 15, 16, 17, 22 and 23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 7, 10, 23 and 29, of copending Application No. 10/804,780. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device taught by both are medical devices for delivering a pulse waveform

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to a target site of a patient comprising identical elements in the above-cited claims, and the method taught by both are methods of delivering a pulse waveform to a target site of a patient comprising identical steps in the above-cited claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

4. Claim 15 is objected to because the word "element" should be inserted after the word "switching" in the second line of the claim. Appropriate correction is required.
5. Claim 23 is objected to because the word "elecytrodes" should be replaced with "electrodes" in line 2 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Imran et al (U.S. 4,614,192). Imran discloses (column 4, lines 15-16) a defibrillator wherein "several electrodes are connected to the patient's heart and the defibrillator circuits." Imran further discloses (column 4, lines 39-41) a "high-voltage energy storage capacitor in the defibrillator." Imran discloses (column 5, lines 8-13) "when the circuits

(28) and (30) detect abnormal cardiac rhythms, they each assert an enabling signal” which eventually “initializes a high-voltage inverter and control circuit (34) in preparation for delivering a defibrillating pulse to the patient’s heart. Each such pulse passes to the heart across electrodes (20) and (22).” See Fig. 1. To keep track of the number of defibrillating pulses issued, (column 5, lines 31-33) “the circuit (34) produces a CT pulse signal each time it issues a defibrillating pulse. The CT pulse signal is used by pulse counting circuitry.” The examiner considers the circuit (34) to be control circuitry, coupled to the energy storage device and the plurality of electrodes, generating the pulse waveform from the stored energy and delivering the pulse waveform to the target site via the polarity of electrodes. The pulse waveform corresponds to multiple signals delivered simultaneously to multiple pathways between the electrodes.

Regarding claims 5, 7 and 8, Imran discloses (column 4, lines 20-21), “the electrodes include a bipolar sensing electrode (18) adapted to be located in the right ventricle” and transcardiac sensing and high-voltage delivery electrodes (20) and (22). “The electrode (20) is adapted to be located in the superior vena cava and the patch electrode (22) is adapted to be connected to the myocardium near the apex of the heart.” The examiner considers this triad of electrodes to be in a Delta configuration about the target site of the patient’s heart; electrode (22) is a non-intracardiac electrode and is considered to be subcutaneous, as it is placed below the patient’s skin.

8. Claims 1, 4, 9 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Stemple (U.S. 4,566,457). Stemple discloses (column 1, lines 47-48) “an electrical circuit for generating energy pulses at two shock electrodes of a defibrillator.” The

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operating circuit of the electrical circuit (column 3, lines 51-52) "includes an energy storage means (1) in the form of a capacitor or a capacitor cascade arrangement." The electrical circuit also comprises a safety circuit (22) that (column 4, lines 4-7) "includes a shunt switch or contact means which is coupled to the patient circuit (23) that is formed by the shock or defibrillation electrodes, by way of voltage barrier means." See Fig. 1. The examiner considers this to be a control circuitry that is coupled to the energy storage device and the plurality of electrodes.

Regarding claims 4 and 9, Stemple discloses (column 4, lines 18-21) "the safety circuit may include an inductor, for example an air coil, which serves for pulse shaping during the defibrillation shock procedure." The examiner considers this to be a smoothing element. The smoothing element is electrically in series with the energy storage means. See Fig. 6.

Regarding claim 17, Stemple discloses (column 6, lines 3-10) a circuit that includes a "discharging line, which is also connected to the capacitors C_1 through C_n [energy storage capacitors] by way of respective switches SE_1 through SE_n connected in series with respective ones of the capacitors. It will be seen therefore that discharge of the capacitor array is effected by way of the discharge line when the switches SL_1 through SL_n are in an open condition and the switches SE_1 through SE_n connected in series with the capacitors are serially closed at given intervals of time. In this case also the serial combination of the individual capacitor voltages, with simultaneous discharge by way of the electrodes (3) and (4), provides for the formation of an individually definable discharge curve." The examiner considers this to be generating a plurality of

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output pulses corresponding to each of a plurality of electrodes, and controlling switching elements associated with each of the plurality of electrodes in a predetermined pattern.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Altman et al (U.S. 4,726,379). Altman discloses (column 4, lines 40-47) "a cardiac pacer comprising a ventricular channel subsystem and an atrial channel subsystem, each subsystem having: a lead for receiving cardiac signals; a sensing circuit for sensing cardiac signals; a stimulator for supplying cardiac stimulating pulses; and a switched capacitor circuit operable to transmit cardiac signals from the lead of the subsystem to the sensing circuit of the subsystem such that the subsystem provides no return current path for stimulating pulses from the stimulator of the other subsystem." The examiner considers this to be generating a plurality of output pulses to each of a plurality of electrodes, and controlling switching elements associated with each of the plurality of electrodes in a predetermined pattern. In view of the structure as disclosed by Altman, the method of operating or using the device would be inherent because it is the normal and logical means by which the device can be used. Altman further discloses (column 12, lines 15-16) a programmable microcontroller that "would include memory storage and a programmed microprocessor." The examiner therefore considers this to be a computer readable medium having computer-executable instructions for performing the above method.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imran et al (U.S. 4,614,192) in view of Belt (U.S. 4,436,093). Imran fails to teach a predetermined phase shift for the multiple signals. Belt however discloses (column 9, lines 44-49) "a sampling rate of four times the power line frequency is provided by the four sampling channels, each having a 90 degree phase relationship to each other. It will be appreciated that a greater number of channels may be employed where greater resolution is required." Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Imran's defibrillator with Belt's signal phase shift in order to achieve greater resolution of the signal provided by the defibrillator.

Regarding claim 3, Imran in view of Belt discloses the claimed invention but does not disclose expressly the value of the predetermined phase shift of the signal. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the phase shift as taught by Belt, with the value of 120 degrees, because the applicant has not disclosed the phase shift value provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the phase shift of 90 degrees as taught by Belt, because the signal of Belt's system is

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adequate for resolution, and nothing prevents Belt's phase shift from being used in the applicant's system. Therefore, it would have been an obvious matter of design choice to modify the defibrillator of Imran in view of Belt to obtain the invention as specified in the claim.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imran et al (U.S. 4,614,192) in view of Kuck et al (U.S. 5,921,923). Imran fails to teach a fourth electrode that can form a Wye configuration about the target site. Kuck however discloses (column 6, lines 31-36) "the first and second electrodes can be electrically connected (through switch element), forming a unified tip electrode. A conventional fourth bipolar signal can be obtained between the unified tip electrode and the third electrode in the second plane along the body axis." Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Imran's defibrillator with Kuck's electrode array in order to create additional signals for diagnostic function within the defibrillator.

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imran et al (U.S. 4,614,192) in view of Belt (U.S. 4,436,093) in further view of Kuck et al (U.S. 5,921,923). Imran and Belt fail to teach a bipolar signal for each of the electrodes. Kuck however discloses (column 3, lines 3-5) a multiple electrode array comprising at least three, mutually spaced apart electrode elements, wherein the spaced apart elements are also "electrically isolated one from the other, so that bipolar signal readings can be obtained between selected electrode pairs." The electrode array can (column 3, lines 20-22) "continuously record multiple electrical events at different

relative orientations, all within a localized area.” Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Imran’s defibrillator with Belt’s predetermined signal and Kuck’s bipolar signal in order to add a diagnostic function to the defibrillator, wherein the diagnostic function has a great resolution for more precise interpretation of the signal.

13. Claims 11, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stemple (U.S. 4,566,457). As to claims 11 and 13, Stemple discloses the claimed invention except for a third pair of switching elements, a third electrode and multiple smoothing elements. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stemple’s defibrillation circuit with a third pair of switching elements, a third electrode and a plurality of smoothing elements, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. See MPEP § 2144.04.

Regarding claim 15, Stemple discloses (column 6, lines 3-10) a circuit that includes a “discharging line, which is also connected to the capacitors C_1 through C_n [energy storage capacitors] by way of respective switches SE_1 through SE_n connected in series with respective ones of the capacitors. It will be seen therefore that discharge of the capacitor array is effected by way of the discharge line when the switches SL_1 through SL_n are in an open condition and the switches SE_1 through SE_n connected in series with the capacitors are serially closed at given intervals of time.” The examiner considers this to be a first energy storage element associated with a first switching

element and a second energy storage element associated with the second switching element.

Regarding claim 16, Stemple discloses (column 4, lines 18-21) "the safety circuit may include an inductor, for example an air coil, which serves for pulse shaping during the defibrillation shock procedure." The examiner considers this to be a smoothing element electrically in series with the energy storage means. See Fig. 6.

14. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stemple (U.S. 4,566,457) in view of Kuck et al (U.S. 5,921,923). Stemple fails to teach a bipolar signal for each of the electrodes. Kuck however discloses (column 3, lines 3-5) a multiple electrode array comprising at least three, mutually spaced apart electrode elements, wherein the spaced apart elements are also "electrically isolated one from the other, so that bipolar signal readings can be obtained between selected electrode pairs." The electrode array can (column 3, lines 20-22) "continuously record multiple electrical events at different relative orientations, all within a localized area." Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stemple's defibrillator circuit with Kuck's bipolar signal in order to add a diagnostic function to the defibrillator.

Regarding claim 14, Kuck discloses (column 6, lines 31-36) "the first and second electrodes can be electrically connected (through switch element), forming a unified tip electrode. A conventional fourth bipolar signal can be obtained between the unified tip electrode and the third electrode in the second plane along the body axis." The examiner considers this to be an output switching element coupled to the control

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circuitry that controls a state of the output switching element to alternate between a Delta configuration and a Wye configuration.

15. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stemple (U.S. 4,566,457) in view of Belt (U.S. 4,436,093). Stemple fails to teach a predetermined phase shift for the multiple signals. Belt however discloses (column 9, lines 44-49) "a sampling rate of four times the power line frequency is provided by the four sampling channels, each having a 90 degree phase relationship to each other. It will be appreciated that a greater number of channels may be employed where greater resolution is required." Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stemple's defibrillator circuit with Belt's signal phase shift in order to achieve greater resolution of the signal provided by the defibrillator.

Regarding claim 19, Stemple in view of Belt discloses the claimed invention but does not disclose expressly the value of the predetermined phase shift of the signal. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the phase shift as taught by Belt, with the value of 120 degrees, because the applicant has not disclosed the phase shift value provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the phase shift of 90 degrees as taught by Belt, because the signal of Belt's system is adequate for resolution, and nothing prevents Belt's phase shift from being used in the applicant's system. Therefore, it would have been an obvious matter of design choice

to modify the defibrillator circuit of Stemple in view of Belt to obtain the invention as specified in the claim.

16. Claims 20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stemple (U.S. 4,566,457) in view of Imran et al (U.S. 4,614,192). Stemple fails to teach a Delta configuration for the electrodes about the target site. Imran however discloses (column 4, lines 20-21), "the electrodes include a bipolar sensing electrode (18) adapted to be located in the right ventricle" and transcardiac sensing and high-voltage delivery electrodes (20) and (22). "The electrode (20) is adapted to be located in the superior vena cava and the patch electrode (22) is adapted to be connected to the myocardium near the apex of the heart." The examiner considers this triad of electrodes to be in a Delta configuration about the target site of the patient's heart; electrode (22) is a non-intracardiac electrode and is considered to be subcutaneous, as it is placed below the patient's skin. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stemple's defibrillation circuit with the Delta configuration of electrodes, including the non-intracardiac electrode and the subcutaneous electrode of Imran in order to administer a more concentrated treatment on a targeted area of the heart.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 5,865,838 to Obel et al, disclosing Low energy implantable atrial defibrillator using multiple electrodes and stimulating rates

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U.S. 6,178,351 to Mower et al, disclosing Atrial sensing and multiple site stimulation as intervention means for atrial fibrillation

U.S. 6,909,916 to Spinelli et al, disclosing Cardiac rhythm management system with arrhythmia classification and electrode selection

U.S. 6,735,472 to Helland, disclosing Method of defibrillating a heart with electrode configurations including a left ventricular defibrillation electrode

U.S. 6,671,546 to Cansell et al, disclosing Impulses or a series of impulses for defibrillation and device to generate them

U.S. 6,449,506 to Sh. Revishvili et al, disclosing Multiphase defibrillator with conductive housing

U.S. 6,085,117 to Griffin, III et al, disclosing Method of defibrillating employing coronary sinus and external patch electrodes

U.S. 5,814,076 to Brownlee, disclosing Apparatus for improved cardiac pacing and sensing using extracardiac indifferent electrode configurations

U.S. 5,584,865 to Hirschberg et al, disclosing Defibrillator with output stage using switching network and three electrode

17. Any inquiry concerning this communication or earlier communications from the


examiner should be directed to Deborah Malamud whose telephone number is (571)

272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3766